

REMARKS

The Laufer et al. reference on form PTO-1449 which was not found with the Information Disclosure Statement is enclosed. Consideration is respectfully requested.

While Applicants respectfully traverse, Claims 10 – 20 have been canceled, without prejudice, as required by the Restriction Requirement. Applicants disagree with the reasons for restriction relating to "additional solid asymmetric particles (step (a) of instant claim 10)." Claim 10 requires no such "additional particles" as claim 10 which is dependent on Claim 1 which provides antecedent basis for "solid asymmetric particles" and is of "comprising" scope.

Claim 1 has been amended to incorporate the subject matter of Claim 3, without prejudice. Claims 2 and 3 have been canceled, without prejudice. Claim 1 as amended recites the preferred range of ZnO. Support for this amendment may be found at page 12 of the Specification.

Care has been taken not to introduce any new matter.

The Present Invention

ZnO particles are used as inorganic sunscreen in the personal care industry because of its broad UV absorbance spectrum and non-toxic properties. However, dispersion of ZnO particles has, prior to the present invention, always been difficult due to aggregation of the nano-particles. The process according to the present invention was designed to ameliorate the problem in the art, and provides, in summary:

A process for incorporating ZnO particles in a cosmetic composition comprised of solid asymmetric particles, preferably stearic acid, comprising:

Melting said solid asymmetric particles to form melted fatty acid;

Adding un-coated ZnO particles to said melted fatty acid to form a mixture of ZnO and fatty acid; wherein said ZnO is added in an amount of about 1 % to about 4 % by weight of said cosmetic composition;

Heating said mixture to a temperature of less than about 80°C for about 5 to about 10 minutes;

Cooling said to a temperature of about 50°C, thereby quenching any reaction between said ZnO and said fatty acid.

Claims Are Not Indefinite Under 35 U.S.C. §112

Applicants respectfully submit that, with reference to Claim 9, it is not necessary to specify the products to which ZnO is converted during the reaction. One skilled in the art would understand that conversion refers to the reduction in the initial amount of the reactant ZnO into its chemical products. As ZnO herein is a pure material, it is not necessary to specify whether conversion is being measured on a weight or molar basis.

Claims Are Not Obvious Under 35 U.S.C. §103

Reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. §103 are respectfully requested in the following remarks.

Claims 1, 2 and 4-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchnick, et al. (U.S. Patent No. 5,441,726) in view of Galley, et al. (U.S. Patent No. 5,609,852). Claims 1, 2 and 4-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchnick, et al. (U.S. Patent No. 5,441,726) in view of Galley, et al. (U.S. Patent No. 5,609,852) and Ramp, et al. (U.S. Patent No. 4,558,086). While Applicants respectfully traverse, these rejections have been rendered moot by the incorporation of the subject matter of Claim 3 into Claim 1.

Mitchnick, et al., in view Galley, et al., and Halls

Claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchnick, et al., in view Galley, et al., and Halls (U.S. Patent NO. 6,267,949). Applicants respectfully traverse.

According to the Office Action, Mitchnick, et al., disclose a creamy foundation composition of the following components:

Composition	40
(1) zinc oxide rods	10 wt. %
(2) talc	the balance
(3) kaolin	12
(4) titanium oxide	13
(5) red iron oxide	1.5
(6) yellow iron oxide	2.0
(7) black iron oxide	0.5
(8) liquid paraffin	15
(9) isopropyl palmitate	10
(10) lanolin alcohol	3
(11) microcrystalline wax	7
(12) ozocerite	8
(13) antiseptic	a suitable amount
(14) perfume	a suitable amount

Further according to the Office Action, the foundation was prepared by mixing components 11 to 14.; The un-coated zinc oxide rods (8% by weight) can be 100nm in diameter (Column 13, lines 20 and 26-27).; Components 7 through 10 are mixed together to form a solution (Column 13, lines 7-28).; The zinc oxide containing component is dispersed in the solution of components 7-10 and heated to 75°C.; Components 1 through 6 (containing 5% by weight stearic acid) are mixed and heated to 80°C to form a solution which is then added to the solution containing zinc oxide to produce an emulsion (Column 13, lines 30-33). ; The emulsion is cooled under stirring to 50°C and the final perfume ingredient is added (Column 13, lines 33-35).; etc.

Further according to the Office Action, the cosmetic preparation of Mitchnick, et al., is comprised of 5% by weight stearic acid and 8% by weight of zinc oxide.; Mixing of these components at a temperature less than about 80°C and cooled under stirring to a temperature of 50°C to quench the reaction between ZnO and stearic acid would

produce the solid asymmetric particles of the instant invention in at least 10% by weight of the composition (instant claim 7). ; etc.

Applicants agree with the Office Action position that Mitchnick, et al., do not expressly teach heating the mixture of ZnO particles and stearic acid to a temperature of less than about 80°C for about 5 to about 10 minutes. Moreover, The ZnO nanoparticles disclosed in Mitchnick, et al. are not obtainable by the process of claim 1. As demonstrated in Example 3 of the present application, in order to confer the unique surface properties, it is necessary that there be incomplete reaction between the ZnO and stearic acid and incomplete reaction can only be assured if the reaction temperature is below 80°C and the reaction is quenched between a time of 5 and 10 minutes (see table 2). The process disclosed in Mitchnick, et al. does not have either of these essential technical features. Contrary to the Examiner's suggestion, the statement in Mitchnick, et al. at column 13 (lines 33-35) that "The emulsion is cooled under stirring to 50°C." does not even imply a time scale, let alone provide a direct and unambiguous disclosure of quenching after a period of 5 to 10 minutes. Furthermore, it is clearly stated in column 13 (lines 4-5) of Mitchnick, et al. that the composition disclosed therein is a creamy foundation, which would not be formed with the solid asymmetric particles according to the present invention.

The present invention is distinguished over Mitchnick, et al. in claiming a process for preparing a cosmetic composition comprising solid asymmetric particles, additionally including the following features:

- (i) mixture of ZnO and fatty acid is heated to a temperature of less than 80°C; and
- (ii) the mixing time is between 5 and 10 minutes; and
- (iii) the addition of ZnO in an amount of about 1% to about 4% by weight of the cosmetic composition.

One skilled in the art would not be motivated to modify the process disclosed in Mitchnick, et al. to thereby arrive at an embodiment falling within the ambit of claim 1 because Mitchnick, et al. has nothing to do with solid asymmetric particles or stearic acid, which pose problems not addressed by Mitchnick, et al. by providing a UV protective composition with improved spreadability and even dispersibility of ZnO (column 1 [line 60] to column 2 [line 14]).

Further according to the Office Action, Galley, et al., provide a general teaching for the preparation of sunscreen compositions comprised of metal oxides such as zinc oxide. ; Galley, et al., disclose that the oil phase components are heated together to 70-75°C and then mixed with the aqueous phase containing the metal oxide for 5-10 minutes. ; The emulsion is then cooled; Galley, et al., disclose that fatty acid soaps, such as potassium stearate, are effective emulsifying agents that can be added to the composition (Column 4, line 52).; Hall discloses sunscreen compositions comprised of nano-size ZnO particles in the preferred range of 0.5-15% by weight (Column 4, lines 52-55).

Even if one skilled in the art were to combine all of the teachings in Mitchnick, et al. with Galley et al. nor Halls et al. , they still would not arrive at an embodiment falling within the ambit of claim 1 because neither Mitchnick, et al. nor the secondary references disclose solid asymmetric particles, or stearic acid, or any of the features (i), (ii) and (iii) set forth herein above. Halls et al. are limited to pigmentary grade zinc oxide. See Example 8-11 (Column 7, lines 1-8).

It is not proper to pick and choose elements of the invention from a variety of references, unless there is some suggestion or motivation to do so. Applicants

respectfully traverse and submit that Halls et al. do no remedy the deficiencies of Mitchnick, et al. in view Galley, et al. Hall, et al. have nothing to do with creams having solid asymmetric particles according to the present invention. The Office Action position notwithstanding, it would not have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition of Mitchnick, et al., using the heating period suggested by Galley, et al., containing zinc oxide in the percent weight range of about 1% to about 4% as suggested by Halls to produce the instant invention. It is not proper to pick and choose elements of the invention from a variety of references, unless there is some suggestion or motivation to do so. The invention must be viewed as a whole. Therefore, the claimed invention, as a whole, would not have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because not every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

The Office Action position notwithstanding, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition containing zinc oxide and stearic acid by the procedure of Mitchnick, et al., using the suggested heating period of 5 to 10 minutes of Galley, et al., to produce metallic soap coated ZnO particles of the instantly claimed invention.

Thus the subject matter of claim 1 and its dependent claims 4-9 is novel and unobvious.

CONCLUSION

In view of the foregoing amendment and comments, applicants request the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,



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Objective Measurement and Self-Assessment of Skin-Care Treatments

Researchers investigate how women perceive measurable skin parameters and cosmetic treatments



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"Dry skin" is not an established scientific term, although it is frequently used — and misused. The term, used by dermatologists and other professionals as well as cosmetic companies, describes one of the most common cosmetic complaints. In addition, each personal-care product manufacturer claims its moisturizing products solves "dry skin." Such products are supposed to give the skin the moisture and/or lubrication it lacks and restore the skin's youthful look.

To find the source of dry-skin discomfort, we tried to establish whether a correlation exists between a woman's estimation of her own facial-skin condition and a set of objective, instrumental measurements. We also investigated the following points:

- Does the subject feel abnormal stratum corneum (SC) conditions, or are they asymptomatic?
- Is the woman's estimation a good guide of the efficacy of skin-care products?

Previous studies of self-assessment: Very little pub-

lished literature correlates subjective assessment and objective measurements. Recently, Akazaki et al found good correlation between the skin's sebum content and the consumer's assessment of skin condition.¹ Self-assessment of water content, however, did not correlate well with the objective results. Another study showed that a clinical assessment of dry skin by experienced examiners correlated with low levels of casual sebum.²

Comparisons of consumers' assessment of product oiliness to measured values of the skin-friction coefficient found changes in skin friction to be inversely proportional to the subjective afterfeel of "greasiness." In other words, the greater the increase in skin friction, the less greasy the user perceives the product to be.¹⁹

A high correlation exists between a skin treatment's success as defined by instrumental measurements and as estimated by consumer satisfaction.³ A Japanese group classified facial skin into four classes: normal, dry, oily and dry/oily (lacking moisturization but oily). The Japanese researchers found good correlation between perceived oiliness and skin-surface lipid quantity. A good correlation also existed between perceived smoothness/roughness and measured TEWL and skin-surface morphology.¹⁸

This article is part of an MD thesis submitted to the Faculty of Medicine, The Hebrew University of Jerusalem, 1993. The Helsinki Committee of the Hadassah University Hospital approved the experiments described here.

Les femmes ne sont pas conscientes du réel degré d'humidité et du pH élevé de la peau au niveau du visage. Par contre, elles perçoivent la sécheresse. Pour traiter cette sécheresse de leur peau et pour y remédier, elles préfèrent avoir recours à des produits cosmétiques riches en huiles.

Frauen sind sich nicht über den aktuellen Feuchtigkeits-Status ihrer Gesicht-Haut oder über den hohen Haut-pH-Wert in der Region des Gesichts bewußt. Stattdessen nehmen Frauen den Mangel an Feuchtigkeit als trockene Haut wahr. Um den als trocken empfundenen Hautzustand zu behandeln, bevorzugen Frauen ein öhlältiges Produkt.

Las mujeres no están conscientes de la condición humectante de su piel facial o el nivel de pH en la piel de la cara. En vez, ellas perciben la falta de grasa en la piel como piel seca. Al tratar la sequedad que sienten, la preferencia de ellas es de un producto que contenga más grasa.

Table 1. Cut-off values and normal ranges of measured parameters

Sebum, $\mu\text{g}/\text{cm}^2$			
	Neck	Face	Forehead
oily/normal	88	142	250
normal/dry	20	20	90
normal values	20-88	20-142	90-250

Moisture (nF)			
	Neck	Face	Forehead
normal/dry	3	3	5
normal values	>3	>3	>5

pH			
	Neck	Face	Forehead
balanced/unbalanced	5.6	5.5	5.2
normal values	<5.6	<5.5	<5.2

Table 2. Components of the products used and their action on the skin

Preparation	Univalent Role
<i>Moisturizer Dermor</i>	
Glycerin	Humectant
Carbomer	
Distilled water (aqua)	
<i>Lubricant Dermor</i>	
Cetostearyl alcohol	
Octyldodecanol (Eutanol G, Henkel)	Adds oiliness to skin
Com oil	
Petrolatum	
Distilled water (aqua)	
<i>Acidifier Dermor</i>	
Lactic-acid	Restores skin pH
Distilled water (aqua)	

Materials and Methods

We included 103 randomly selected female volunteers in the study. Ages ranged from 19 to 82 years. We asked the women to fill out questionnaires evaluating the skin condition on their forehead, face and neck. They also gave information about their background, cosmetic treatment habits and expectations regarding a cosmetic product.

After they completed the questionnaire, we examined their skin. Before the examination, we instructed the women not to use any skin-care product in the previous 12 hours and

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to avoid washing their faces within the 3 hours immediately prior to the examination.

We evaluated the skin using an instrument that measures three important parameters:⁴

- **Sebum.** A photometer measured the transparency of a glass slide that has been attached to the skin for a measured time.
- **Moisture/water content.** We measured the skin's capacitance at 16 Hz.⁵
- **pH.** A planar electrode measured skin-surface pH.^{6,7}

The instrument read both the absolute measurements and whether the value is within the normal range (Table 1). We calibrated the instrument with the statistically normal values of a large population 20-29 years old. The normal value for each measured parameter is known in the literature and in agreement with the instrument's calibration.^{8,9,10,11} Previous research established the reliability of this measurement method.^{12,13}

Upon completion of the examination, we prescribed a suitable skin product for each participant.⁹ Each of the products claims to correct only one of the measured parameters (Table 2). We asked the women to apply the product twice daily on the face and neck.

We asked each subject to fill out a second questionnaire 3 weeks later, indicating her compliance, her level of satisfaction with the product she used, and an estimation of her skin condition after the treatment. We then examined the skin using the same instrument under the same conditions as before. With some women, we conducted a third examination after treatment with a second product.

We analyzed the results statistically using the chi-square test.

Results

We found a significant statistical correlation between the complaint of dry skin and a lack of sebum ($p<0.05$, Table 4). However, we saw no significant correlation between per-

¹Skin Tester² produced by IMS Ltd., Israel.

²The Dermor line, commercially available from Diteks Ltd., P.O.B.

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Table 3. Parameters measured, sorted by whether the affected women are pre- or postmenopausal

	Total	Complaints of dry skin		Low sebum		Unbalanced pH	
		Pre-menopausal	Post-menopausal	Pre-menopausal	Post-menopausal	Pre-menopausal	Post-menopausal
Forehead	16/103	4/69	12/34	34/69	26/34	13/69	16/34
Face	21/103	11/69	10/34	44/69	30/34	16/69	17/34
Neck	15/103	5/69	10/34	34/69	28/34	10/69	12/34

Table 4. Proportions of women showing selected two-parameter combinations

	Forehead	Face	Neck
Dry skin*/low sebum*	15/16	21/21	13/15
High pH*/low sebum*	19/29	28/33	15/22
High pH*/low moisture*	26/29	28/33	15/22

*Instrumental result

*Self-assessment

Table 5. Measured improvement of oil (sebum) levels and moisturization

	Oiliness		Moisturization	
	with moisturizer	with lubricant	with moisturizer	with lubricant
Forehead	14/57	9/52	18/57	9/52
Face	14/57	7/52	23/57	12/52
Neck	16/57	19/52	14/57	16/52

ceived dryness and either lack of skin moisture or higher-than-normal pH. In addition, except for the complaint of dry skin, we found no agreement between our objective measurements and a woman's self-evaluation of the skin condition on different parts of her face.

The percentage of women suffering from a lack of sebum is significantly greater after menopause (Table 3). As we would expect, significantly more women also complained of dry skin after the onset of menopause.

More women have a higher-than-normal skin pH after menopause. We did find a correlation between a high pH and a lack of either sebum or moisture (Table 4).

The moisturizer treatment satisfied only 32 of 57 (56%) women and the skin lubricant satisfied 47 of 52 (90%); this difference is statistically significant. However, the differences between measured improvements in women using the moisturizer or the lubricant are not significant (Table 5).

Self-Assessment vs. Measured Values

Skin moisture: The epidermis is the major barrier against water loss. Blanke emphasized the importance of water in the SC.²⁴ He found water to be the principle skin plasticizer.

Under most environmental conditions in temperate climates, the SC does not dry out and become brittle. In pathological conditions, when the environmental conditions are extreme, or when the barrier function of the skin is disrupted, transepidermal water loss (TEWL) increases and the skin dries out.²⁵

Too much water also harms skin. Superhydrated skin supports increased bacterial populations and qualitative

changes in the flora. The skin's pH also increases gradually to abnormal levels with excess moisture.²²

Despite the critical nature of water content, deficient water in the SC was asymptomatic in our subjects; the complaint of dry skin did not correlate with a measured lack of water. Our study implies, therefore, that women can only assess lack of moisture by instrumental measurement.

Japanese researchers drew a similar conclusion from correlations between subjective evaluations and physical observations in 174 female volunteers. The subjective dryness factor (lack of water) did not correlate well with objective data determined by conductance and exfoliative measurements.¹

Skin oiliness: Sebum's role in skin health is not clear. Men retain a relatively constant sebum content on the skin throughout their lives. By contrast, sebum levels on female facial skin drop with age, with the major decrease occurring after menopause.

In our study, the complaint of dry skin correlated strongly with a lack of sebum. Of the women complaining of dry skin, 95% had low sebum levels on the forehead, 100% on the face and 87% on the neck (Table 4). More postmenopausal than premenopausal women complained of dry skin (Table 3).

The Japanese researchers also asked their subjects about skin oiliness and skin conditions associated with oiliness, such as pimples.¹ They showed a good correlation between subjective and objective results, concluding that individuals are well-aware of the degree of oil on their skin. In particular, the women in this Japanese study are concerned about controlling or correcting excess oil on their skin rather than a lack of oil.

The combined conclusion of the Japanese research and our study is that individuals can correctly evaluate both excess oiliness and lack of oiliness. Another Japanese study supports this view,²³ as does the good correlation existing between skin-condition assessments by experienced skin examiners and measured levels of sebum.²⁴

Skin pH: A newborn infant's skin has a neutral or basic pH, but the skin reaches an acid pH during the first week of life. Its pH remains acidic and stable until old age.¹¹

Lack of proper skin acidity can result from skin disease or using unsuitable skin products. The number of propionobacteria colonies on the skin increases with high pH.²⁵ With old age, high pH is associated with the lack of skin elasticity.²⁶ High pH also correlates with high TEWL, which correlates, in turn, with low SC moisture levels.²⁷ By contrast, the degree of skin irritation does not correlate with other biophysical factors, such as TEWL, sebum levels or epidermal turnover.²⁸

These findings imply that the skin's acid mantle is important to skin health.¹⁰ Among our study participants, high pH was more common in the postmenopausal subgroup (Table 3). Our finding differs from that of Zlotogorski who showed no change in skin pH until the age of 80 years.²⁹ The discrepancy might be due to chronic use of unsuitable skin products by our subjects before their participation in our study group.

High pH seems to be asymptomatic, not correlated to any specific skin self-assessment. The only way to detect high pH is through objective measurement. We showed an association between high pH and low sebum and a correlation

between high pH and low moisture (Table 4). Whether this is a cause-and-effect relationship is still unproven. The correlation between high pH and low moisturization has been demonstrated before.²⁵

Consumer Satisfaction

Consumer satisfaction depends upon many factors, many of which are totally unrelated to the product's suitability or efficiency. A recent study showed good correlation between moisturizing efficiency and subjective evaluation.² This study, however, used products containing both oily ingredients and humectants. Therefore, the effect of humectant action alone cannot be evaluated. The authors showed that excess oiliness occurred in their subjects.

In our 3 week study, we examined the skin 12 hours after the last application of an equivalent cosmetic product. The changes observed might be long-term changes caused by the product. Moreover, the volunteer's compliance with the treatment is always variable. Therefore, we cannot draw firm conclusions about the efficiency of the skin-care products used in this study.

From the viewpoint of consumer satisfaction, significantly more women were satisfied with the lubricant than with the moisturizer. This finding agrees with our statement that women are aware of facial oiliness. It also supports our finding that women are not aware of the actual moisturization of their skin.

We emphasize here that, while we used an oil-free moisturizer, the lubricant does supply oil. Because we have shown that the dry-skin complaint is related to a lack of sebum, the smaller percentage of women satisfied with the moisturizer may result from its failure to supply additional oil. A product that replenishes skin oils may well be what the consumer is seeking in a cosmetic product. This may be true even though, according to our present understanding of skin physiology, the moisturizing ability is more important, especially in cases in which SC dryness is a portion of clinical symptoms.

Cosmetics sales to individuals could rely on objective, validated instrumental measurements: instruments are available and the normal representative range of these instruments is known.^{3,6,8,10-12,27} Absence of such measurements on individual consumers may lead to chronic use of a product unsuitable for that individual, perhaps even one that will not keep the skin's moisture content and surface pH within normal ranges. Oiliness or lack of oil from a cosmetic product probably does not represent a problem because, according to our studies, women are well-aware of the oily status of their facial skin, although they are unaware of its water content.

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